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AT51975
A1U524



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Field
Operations

October 1997

Meat and Poultry Inspection Regulations

Change 97-4

CHANGE TRANSMITTAL SHEET

- ☐ DIRECTIVE
☐ REVISION
☐ AMENDMENT
☒ OTHER

CHANGE 97-4
MEAT AND POULTRY INSPECTION REGULATIONS

97-4

9-24-97

I. PURPOSE

This document transmits changes to Parts 304, 308, 317, 318, 319 and 381 of the MPI Regulations. These changes were published in the Federal Register on August 25, 1997 (62 FR 45016, Docket No. 95-032F), titled Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove

Pages 13,14,21,22, 23, 23a
94b, 97, 98, 98a, 98b,
100a, 100b, 119, 120, 136g, 136h,
136ggg, 136hhh, 136iii, 136jjj,
136mmm, 138nnn, 139, 140, 140a,
140b, 187, 188, 199 and 200

Insert

Pages 13, 14, 21, 22, 23, 23a,
94b, 97, 98, 98a, 98b,
100a, 100b, 119, 120, 136g,
136h, 136ggg, 136hhh, 136iii,
136jjj, 136mmm, 136nnn, 139,
140, 140a, 140b, 187, 188,
199, 200 and 200a

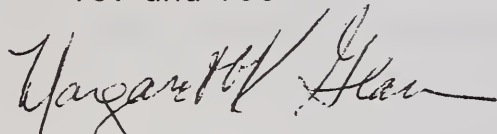
EFFECTIVE DATE: 9/24/97

This covers changes effective as of September 24, 1997.

SUBCHAPTER C - MANDATORY POULTRY PRODUCTS INSPECTION

Pages 15, 16, 17, 18, 19, 20, 21,
22, 23, 24, 24a, 24b, 24c, 29, 30
31a, 62c, 62d, 70a, 70b, 71, 72,
72a, 72b, 117, 118, 155, 156,
157 and 158

Pages 15, 16, 17, 18, 19, 20, 21
22, 23, 24, 24a, 29, 30, 31, 31a,
62c, 62d, 70a, 71, 72, 72a, 72b,
117, 118, 155, 156, 157 and 158



Deputy Administrator
Office of Policy, Program
Development and Evaluation

Attachment

PART 304-APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 304.1 Application for inspection.

(a) Before the inspection is granted, each person conducting operations at an establishment subject to the Act, whether tenant, subsidiary, or landlord, shall make application therefor to the Administrator as provided for in this part.

(b) Every application under this section shall be made on an official form furnished by the Program, available from any Regional Director identified in § 301.2(kkk) of this subchapter, and shall be completed to include all information requested. Trade names of the applicant for labeling purposes, shall be inserted in the appropriate blank in the application. Each applicant for inspection will be held responsible for compliance with the Act and the regulations in this subchapter if inspection is granted. Preparation of product and other operations at the establishment for which inspection is granted may be conducted only by the applicant named in the application.

(c) In cases of change of ownership or location, a new application shall be made.

§ 304.2 Information to be furnished; grant or refusal of inspection.

(a) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

(b) The Administrator is authorized to grant inspection upon his determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he determines that it does not meet the requirements of this part or the regulations in Parts 305, 307, and 308 of this subchapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in Parts 316 and 317 of this subchapter. When inspection is refused for any reason, the applicant shall be informed of the action and the reasons therefor and afforded an opportunity to present his views.

(c) Inspection may also be refused in accordance with section 401 of the Act and the applicable rules of practice.

(d) (1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970, (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(§ 304.2 (a)(1) continued)

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date. Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

* (e) Inspection may be refused in accordance with humane slaughter and handling provisions of the Act (21 U.S.C. 603(b)) and the applicable rules of practice. *

PART 308-SANITATION

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 308.1 Examination and specifications for equipment and sanitation prior to granting inspection.

Prior to the inauguration of inspection, an examination of the establishment and premises shall be made by a Program employee and the requirements for sanitation and the necessary facilities for inspection shall be specified by him in accordance with the regulations in this part and Part 307 of this subchapter.

* § 308.2 RESERVED. *

§ 308.3 Establishments; sanitary condition; requirements.

(a) Official establishments shall be maintained in sanitary condition, and to this end the requirements of this section shall be complied with.

(b) There shall be abundant light, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary condition.

(c) There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with traps and vents approved by the circuit supervisor.

(d)(1) The water supply shall be ample, clean, and potable, with adequate facilities for its distribution in the plant and its protection against contamination and pollution. Every establishment shall make known and, whenever required by the circuit supervisor, shall afford opportunity for inspection of the source of its water supply, the storage facilities, and the distribution system. Equipment using potable water shall be so installed as to prevent back-siphonage into the potable water system. Nonpotable water is permitted only in those parts of official establishments where no edible product is handled or prepared, and then only for limited purposes such as on ammonia condensers not connected with the potable water supply, in vapor lines serving inedible product rendering tanks, in connection with equipment used for hashing and washing inedible products preparatory to tanking, and in sewer lines for moving heavy solids in the sewage. Nonpotable water is not permitted for washing floors, areas, or equipment involved in trucking materials to and from edible product departments nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. In all cases, nonpotable waterlines shall be clearly identified and shall not be cross-connected with the potable water supply unless this is necessary for fire protection and such connection is of a type with an adequate break to assure against accidental contamination, and is approved by local authorities and by the circuit supervisor.

(2) The circuit supervisor may permit the reuse of water in vapor lines leading from deodorizers used in the preparation of lard and similar edible product and in equipment where such water is used to thermally process canned product packed in hermetically sealed containers, provided:

(i) The reuse is for the identical original purpose.

(ii) All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water are so constructed and installed so they can be cleaned and drained, and are kept clean.

(§ 308.3(d)(1) continued)

(3) Approval for the reuse of water other than as specified in paragraph (d)(2) of this section or in § 318.305(h) shall be obtained from the Administrator in specific cases.

(4) An ample supply of water at not less than 180° F. shall be furnished and used for the cleaning of inspection equipment and other equipment, floors, and walls which are subject to contamination by the dressing or handling of diseased carcasses, their viscera, and other parts. Whenever necessary to determine compliance with this requirement, conveniently located thermometers shall be installed by the operator of the official establishment to show the temperature of the water at the point of use.

(5) Hot water for cleaning rooms and equipment other than those mentioned in subparagraph (4) of this paragraph shall be delivered under pressure to sufficient convenient outlets and shall be of such temperature as to accomplish a thorough cleanup.

(e) The floors, walls, ceilings, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish as will make them susceptible of being readily and thoroughly cleaned. The floors shall be kept watertight. The rooms and compartments used for edible product shall be separate and distinct from those used for inedible product.

(f) Rails should be located and passageway space provided so that exposed product does not come in contact with posts, walls, and other fixed parts of the building, or with barrels, boxes, and other containers trafficked through holding and operating areas. Exposed product shall not be placed or stored beneath carcasses in coolers or holding areas.

(g) The rooms and compartments in which any product is prepared or handled shall be free from dust and from odors from dressing and toilet rooms, catch basins, hide cellars, casing rooms, inedible tank and fertilizer rooms, and livestock pens.

(h) Every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from official establishments. The use of poisons for any purpose in rooms or compartments where any unpacked product is stored or handled is forbidden, except under such restrictions and precautions as are prescribed by the regulations in this part or by the circuit supervisor in specific cases. The use of insecticides, rodenticides, and similar pest control substances in hide cellars, inedible product departments, outbuildings, or similar places, or in storerooms containing canned or tierced products is not forbidden but only those approved by the Administrator may be used. Socalled rat viruses shall not be used in any part of an establishment or the premises thereof.

(i) Dogs and cats shall be excluded from the interior of official establishments; however, dogs may be permitted on the outer premises for guard purposes.

§ 308.4 Sanitary facilities and accommodations; specific requirements.

Adequate sanitary facilities and accommodations shall be furnished by every official establishment. Of these, the following are specifically required:

(a) Dressing rooms, toilet rooms, and urinals shall be sufficient in number, ample in size, and conveniently located. The rooms shall be provided with facilities to provide abundant light of good quality and well distributed. They shall be properly ventilated, and meet all requirements of the regulations in this part as to sanitary construction and equipment. They shall be separate from the rooms and compartments in which products are prepared, stored, or handled. Where both sexes are employed, separate facilities shall be provided.

(b) Acceptable lavatories, including running hot and cold water, soap, and towels, shall be placed in or near toilet and urinal rooms and also at such other places in the establishment as may be essential to assure cleanliness of all persons handling any product.

(c) Toilet soil lines shall be separate from house drainage lines to a point outside the building and drainage from toilet bowls and urinals shall not be discharged into a grease catch basin.

(d) Properly located facilities shall be provided for cleansing and disinfecting utensils and hands of all persons handling any product.

§ 308.5 Equipment and utensils to be easily cleaned; those for inedible products to be so marked; PCB-containing equipments.

* (a) Equipment and utensils used for preparing or otherwise handling any edible product or ingredient thereof in any official establishment shall be of such material and construction as, will facilitate their thorough cleaning and insure cleanliness in the preparation and handling of all edible products and otherwise avoid adulteration and misbranding of such products. In addition

1 A list of approved pest control substances is available upon request to Scientific Services, Meat and Poultry Inspection, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

* to these requirements, equipment and utensils shall not in any way interfere with or impede inspection procedures. Receptacles used for handling inedible material shall be of such material and construction that, their use will not result in adulteration of any edible product or in insanitary conditions at the establishment, and they shall bear conspicuous and distinctive marking to identify them as only for such use and shall not be used for handling any edible products.

(b) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official establishment shall not contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and nonfood processing equipment and machinery, and any replacement parts for such equipment and machinery. Totally enclosed capacitors containing less than 3 pounds of PCBs are exempted from this prohibition.

Institute of Standards and Technology Handbook 44, "Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices," 1994 Edition, October 1993, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. It is also available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, D.C. 20408.

- (b) All scales used to weigh meat products sold or otherwise distributed in commerce or in
* States designated under section 301(c) of the Federal Meat Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh meat products unless it has been found upon test and inspection, as specified in NIST Handbook 44, to provide accurate weight. If a scale is reinspected or retested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested by a USDA official, or a State or local government weights and measures official, or State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a retain tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

§ 317.21 Scales: Testing of.

(a) The operator of each official establishment that weighs meat food products shall cause such scales to be tested for accuracy, in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and monitored by an authorized USDA program official.

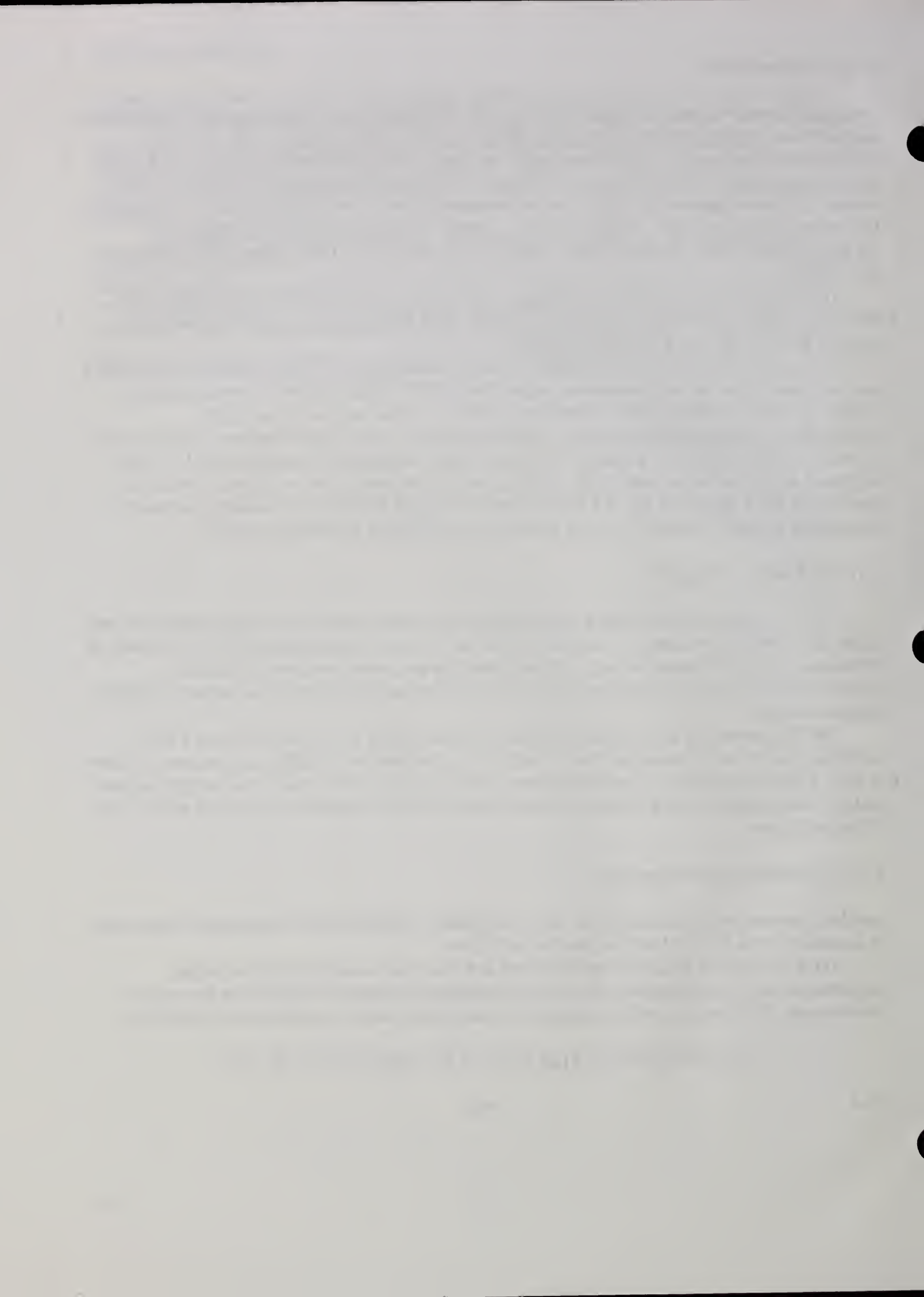
- (b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority
* or from a State registered or licensed scale repair firm or person, or shall have a net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with § 318.4 of this subchapter.

§ 317.22 Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with § 317.19 shall be handled as follows:

- (a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section and be reinspected, in accordance with the requirements of this Part.

THE REVERSE OF THIS PAGE IS INTENDED TO BE BLANK.



from use the labeling or container of the product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

§ 318.3 Designation of places of receipt of products and other articles for reinspection

Every official establishment shall designate, with the approval of the circuit supervisor, a dock or place at which products and other articles subject to reinspection under § 318.2 shall be received, and such products and articles shall be received only at such dock or place.

* § 318.4 Preparation of products to be officially supervised; responsibilities
* of official establishments; establishment-operated quality control.

(a) All processes used in curing, pickling, rendering, canning, or otherwise preparing any product in official establishments shall be supervised by Program employees unless such preparation is conducted as a custom operations exempted from inspection under § 303.1(a)(2) of this subchapter in any official establishment or consists of operations that are exempted from inspection under § 303.1(d) of this subchapter and are conducted in a retail store in an establishment subject to inspection only because the State or Territory in which the establishment is located is designated under paragraph 301(c) of the Act. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) Applying for Total Plant Quality Control. Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the

establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those Parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action--ranging from the least to most severe: Provided, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

* (d) Partial Quality Control Programs. (1) Any owner or operator of an official *
* establishment preparing meat food products who is required to have a quality control program *
* for a product, operation, or part of an operation shall make the written program and data and *
* information generated by the program available to Program employees. *

* (2)(i) This quality control program shall include, as appropriate for the product, operation, *
* or part of an operation which the program concerns, detailed information on: raw material *
* control, the critical check or control points, the nature and frequency of tests to be made, the *
* charts and records that will be used, the length of time such charts and records will be *
* maintained in the custody of the official establishment, the limits which will be used and the *
* points at which corrective action will be taken to prevent recurrence of a loss of control, and *
* the nature of the corrective action--ranging from the least to the most severe. *

* (ii) This quality control program shall ensure that the product, operation, or part of an *
* operation which it concerns is in control and that applicable product or label limits are being *

met. Process control is to be determined by generally recognized statistical process control procedures limits which will be used and the points at which corrective action will occur, and the nature of the corrective action--ranging from the least to the most severe.

(e) Evaluation and Approval of Total Plant Quality Control.

(1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator on the basis of the evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities of the Act.

(f) Labeling Logo. Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Parts 316 and 317 of this Subchapter.



* (g) Termination of Total Establishment Quality Control. *

* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator. *

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

* (3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date, or for at least 2 months from the termination date in the case of a partial quality control program. *

(h) Operating Schedule Under Total Plant Quality Control.

(1) An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permission will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code makers that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and facsimile of the code marks and their meaning shall be provided to the inspector.

(2) Application. Applications shall be submitted to the Regional Director and shall specify how the conditions in § 318.4(h)(1) have been or will be met.

with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to assure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat food product provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Pumped bacon subsequently produced shall not be retained because of nitrosamines if the operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department: Provided, however, That if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of The product. All tests of pumped bacon for nitrosamines under this subparagraph shall be made on pumped bacon cooked at 340°F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in the sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

(3) Notwithstanding the provisions of paragraph (b)(1), sodium nitrite may be used at:

- (i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the establishment has a partial quality control program as provided in § 318.4(d) that results in compliance with this provision, or
- (ii) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as Pediococcus acetolactii or other bacteria demonstrated to be equally effective in preventing the growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in § 318.4(d) that results in compliance with this provision.

(4) The Department shall collect samples of bacon from plants producing under paragraph (b)(3) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(2) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10ppb. In the event of a presumptive positive result, the plant shall become subject to the provisions of paragraph (b)(2) of this section.

(5) Immersion cured bacon. Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(6) Bacon made with dry curing materials. With respect to bacon dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

(c) Under appropriate declaration as required in Parts 316 and 317 of this subchapter, the following substances may be added to products:

(1) Common salt, approved sugars (sucrose (cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids, corn syrup and glucose syrup), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other substances specified in the chart in subparagraph (4) of this paragraph may be added to products under conditions, if any, specified in this part or in Part 317 of this subchapter.

(2) Other harmless artificial flavorings may be added to products with the approval of the Administrator in specific cases.

(3) Coloring matter and dyes other than those specified in the chart in subparagraph (4) of this paragraph, may be applied to products, mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(4) The substances specified in the following chart are acceptable for use in the preparation of products, provided they are used for the purposes indicated, within the limits of the amounts stated and under other conditions specified in this part and Part 317 of this subchapter. In addition to the substances listed in the following chart, Part 319 of this subchapter specifies other substances that are acceptable in preparing specified products.

Class of substance	Substance	Purpose	Products	Amount
	Sodium pyrophosphate.	do	do	Do.
	Sodium silicates (ortho, meta, and sesqui).	do	do	Do.
	Sodium sulfate.	do	do	Do.
	Sodium tripolyphosphate.	do	do	Do.
	Sucrose.	do	do	Do.
	Triethanolamine dodecylbenzene sulfonate.	do	do	Do.
	Trisodium phosphate.	do	do	Do.
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination, under quality control.	To delay discolora- tion.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sg inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed,

*

*

Class of substance	Substance	Purpose	Products	Amount
				singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751) .
	d- and dl-alpha-tocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon.	500 ppm; by injection or surface application.
	Potassium sorbate.	To retard mold growth.	Dry sausage.	10 percent in water solution may be applied to casings after stuffing or casings may be dipped in a 10 percent water solution prior to stuffing.

(E) Provided daily group sampling is in effect pursuant to the provisions of paragraph (b)(1) of this section, and provided further the Product Value is -1.65 or less (e.g., -1.66), the affected lot (if within the official establishment) and all subsequent lots of like product prepared by and still within the official establishment shall be U.S. retained and further evaluated under paragraph (c). Except for release of individual lots pursuant to paragraph (c)(1), subsequently produced lots of like product shall continue to be U.S. retained until discontinued pursuant to paragraph (c)(2).

(c) Compliance procedure during product retention. When a product lot is U.S. retained under the provisions of paragraph (b)(2) of this section, the Department shall collect three randomly selected samples from each such lot and analyze them individually for PFF content. The PFF content of the three samples shall be evaluated to determine disposition of the lot as provided in paragraph (c)(1) of this section and the action to be taken on subsequently produced lots of like product as provided in paragraph (c)(2) of this section.

(1) A product lot which is U.S. retained under the provisions of paragraph (b)(2) of this section may be released for entry into commerce provided one of the following conditions is met:

(i) The average PFF content of the three samples randomly selected from the lot is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105. Further processing to remove moisture for the purpose of meeting this provision is permissible. In lieu of further analysis to determine the effects of such processing, each 0.37 percent weight reduction due to moisture loss resulting from the processing may be considered the equivalent of a 0.1 percent PFF gain.

(ii) The lot of the product is relabeled to conform to the provisions of § 319.104 or § 319.105, under the supervision of a program employee.

(iii) The lot is one that has been prepared subsequent to preparation of the lot which, under the provisions of paragraph (c)(2) of this section, resulted in discontinuance of U.S. retention of new lots of like product.

Such lot may be released for entry into commerce prior to receipt of analytical results for which sampling has been conducted. Upon receipt of such results, they shall be subjected to the provisions of paragraphs (b)(2)(i) and (c)(2) of this section.

(2) The PFF content of three randomly selected samples from each U.S. retained lot shall be used to maintain the Product Value described in paragraph (b)(2)(ii). The manner and effect of such maintenance shall be as follows:

(i) Find the average PFF content of the three samples.

(ii) Determine the difference between that average and the applicable minimum PFF percentage requirement of § 319.104 or § 319.105. The resulting figure shall be negative when the average of the sample results is less than the applicable minimum PFF percentage requirement and shall be positive when the average of the sample results is greater than the applicable minimum PFF requirement.

(iii) Divide the resulting figure by the standard deviation assigned to the product's Group in paragraph (b)(1)(ii) of this section, to find the standardized difference.

(iv) Use the lesser of 1.30 and the standardized difference as the Sample Value.

(v) Add the first Sample Value thus calculated to the latest Product Value calculated under the provisions of paragraph (b)(2)(ii) of this section to find the new Product Value. To find each succeeding Product Value, add the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When the addition of a Sample Value to an existing Product Value results in a figure greater than 1.15, the Product Value shall be 1.15 and all previous Sample Values shall be ignored in determining future Product Values.

(vi) New lots of like product shall continue to be retained pending disposition in accordance with paragraph (c)(1) of this section until, after 5 days of production, the Product Value is 0.00 or greater, and the PFF content of no individual sample from a U.S. retained lot is less than the Absolute Minimum PFF requirement specified in paragraph (b)(2)(I) of this section. Should an individual sample fail to meet its Absolute Minimum PFF requirement, the 5-day count shall begin anew.

(vii) When U.S. retention of new lots is discontinued under the above provisions, maintenance of the Product Value shall revert to the provisions of paragraph (b)(2)(ii) of this section.

(3) For purposes of this section, the plant owner or operator shall have the option of temporarily removing a product from its Product Group, provided product lots are being U.S. retained, as produced, and provided further that the average production rate of the product, over the 8-week period preceding the week in which the first U.S. retained lot was prepared, is not greater than 20 percent of the production rate of its Group. When a product is thus removed from its Group, analytical results of product samples shall not cause daily sampling of the Group. When pursuant to paragraph (c)(2)(vi) of this section, new lots of the product are no longer being U.S. retained, the product shall again be considered with its Group.

(d) Adulterated and misbranded products. Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section l(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section l(n) of the Act (21 U.S.C. 601(n)).

* (e) Quality control. Cured pork products bearing on their labeling the statement "X% of
* Weight is Added Ingredients" shall be prepared only under a quality control system or program in accordance with § 318.4 of this subchapter. With respect to any other cured pork product, official establishments may institute quality control procedures under § 318.4 of this subchapter. Cured pork products produced in such establishments may be exempt from the requirements of this section, provided inplant quality control procedures are shown to attain the same or higher degree of compliance as the procedures set forth in this section; provided, however, that all cured pork products produced shall be subject to the applicable Absolute Minimum PFF content requirement, regardless of any quality control procedures in effect.

§ 318.20 Use of animal drugs.

Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration, unless otherwise determined by the Administrator and listed herein.

(§ 318.306(b) continued)

(2) Batch agitating retorts. In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) Processing in steam/air mixtures. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual process time and temperature. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) Atmospheric cookers.

(1) Batch-type systems. For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) Continuous-type systems. Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

[Approved by the Office of Management and Budget under control number 0583-0015]

§ 318.307 Record Review and Maintenance.

(a) Process records. Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initiated and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) Automated process monitoring and record keeping. When requested by an establishment, the Administrator will consider the approval of automated process monitoring and recordkeeping systems. Any approved system, alone or in combination with written records, shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 318.306.

(c) Container closure records. Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(§ 318.307 continued)

(d) Distribution of product. Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) Retention of records. Copies of all processing and production records required in § 318.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

[Approved by the Office of Management and Budget under control number 0583-0015]

§ 318.308 Deviations in Processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

* (b) Deviations in processing (or process deviations) shall be handled under quality control as provided in paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section. *

* (c) Any partial quality control program or any portion of a total quality system for handling process deviations shall be prepared in accordance with § 318.4 of this subchapter. *

(d) Handling process deviations without an approved quality control program.

(1) Deviations identified in process. If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or,

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 318.302(a) and (b) and is filed with the inspector in accordance with § 318.302(c); or,

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(a) A complete description of the deviation along with all necessary supporting documentation;

(b) A copy of the evaluation report; and,

(c) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with (iii) shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with § 318.308(d)(1)(iii) and (iv) or in accordance with the following procedures:

(a) Emergency stops.

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 318.302(b)) before the retort is

before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked or reprocessed or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ttt) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 318.306.

(b) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10°F (or 5.5°C) either, (i) all containers in the retort shall be given an emergency still process (developed per § 318.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process (developed per § 318.302(b)) shall be used before container entry to the retort is restated; or (iii) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 318.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) For temperature drops 10°F (or 5.5°C) or more, all containers in the retort shall be given an emergency still process (developed per § 318.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 318.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) Deviations identified through record review. Whenever a deviation is naked during review of the processing and production records required by § 318.307(a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(e) Process deviation file. The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 318.307(e) and shall be made available to Program employees upon request.

[Approved by the Office of Management and Budget under control number 0583-0015]

§ 318.309 Finished Product Inspection.

- * (a) Finished product inspections shall be handled under quality control as provided in paragraph (b) or paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section. *
- * (b) Any partial quality control program for finished product inspection shall be prepared in *
- * accordance with § 318.4 of this Part. *
- * (c) That portion of a total quality control system for finished product inspection shall be *
- * prepared in accordance with § 318.4 of this Part. *
- (d) Handling finished product inspections without an approved quality control program.
- (1) Incubation of shelf stable canned product.
- (i) Incubator. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.
- (ii) Incubation temperature. The incubation temperature shall be maintained at $95 \pm 5^{\circ}\text{F}$ ($35 \pm 2.8^{\circ}\text{C}$). If the incubation temperature falls below 90°F (or 32°C) or exceeds 100°F (or 38°C) but does not reach 103°F (or 39.5°C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103°F (or 39.5°C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.
- (iii) Product requiring incubation. Shelf stable product requiring incubation includes:
 - (a) Low acid products as defined in § 318.300(m); and
 - (b) Acidified low acid products as defined in § 318.300(b).
- (iv) Incubation samples.
 - (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.
 - (b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.
 - (c) Only normal-preparing containers shall be selected for incubation.
- (v) Incubation time. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.
- (vi) Incubation checks and record maintenance. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 318.307 (e).
- (vii) Abnormal containers. The finding of abnormal containers (as defined in § 318.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products in accordance with § 319.6.

(b)-(d) [Reserved]

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids present in "Mechanically Separated (Species)" shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. For purposes of this paragraph, essential amino acid content includes isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine content, and the total amino acids present include isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, histidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine, and hydroxproline content.

* (2) A prerequisite for label approval for products consisting of or containing *
* "Mechanically Separated (Species)" is that such "Mechanically Separated (Species)" shall *
* have been produced by an establishment under an establishment quality control system. Such *
* a plant quality control system shall provide the controls and information necessary to assure *
that the product will meet the requirements described in § 319.5(a) and to enable
establishment personnel and program employees to monitor the system for effectiveness.
The system shall include a written description of the methods used by the establishment to
maintain uniformity of the raw ingredients used in manufacturing product, to control the
handling and processing of the raw ingredients and the finished product, and shall contain
provisions for chemical analyses of the product and other procedures to determine and assure
compliance with standards for the product. For purposes of this paragraph, a lot shall consist
of the "Mechanically Separated (Species)" designated as such by the operator of the
establishment or his or her agent from the product produced from a single species of livestock
in no more than one continuous shift of up to 12 hours. All units of any lot must be available
for inspection by program employees. Analysis of a sample of at least 1 pound from each lot
to verify contents of fat, protein, and calcium in "Mechanically Separated (Species)" shall be
performed by the operator of the establishment or his or her agent to assure that finished
product will meet the requirements in § 319.5(a), except that such analyses with respect to fat,
protein, and calcium content shall be required to be performed with respect to only one
randomly selected lot of every five lots if the preceding ten analyses and all such analyses
performed by the Department during the preceding ten analyses period establish compliance
with the requirements of § 319.5(a), and that no analyses with respect to fat or protein content
shall be required where the finished product is represented as product for processing. An
analysis of a sample of at least 1 pound to verify essential amino acid content and/or protein
efficiency ratio in "Mechanically Separated (Species)" shall be performed by the operator of
the establishment or his or her agent at the rate of at least one per month during production to
assure that finished product will meet the requirements of § 319.5(a), except that such

analyses with respect to essential amino acid content and/or protein efficiency ratio shall be required to be performed only once every 6 months if the preceding three analyses and all such analyses performed by the Department during the preceding three analyses period establish compliance with the requirements of § 319.5(a). Finished product samples shall be analyzed in accordance with "Official Methods of Analysis of the Association of Official Analytical Chemists," (AOAC)," 15th edition, 1990, §§ 960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or if no AOAC method is available, in accordance with the "Chemistry Laboratory Guidebook," U.S. Department of Agriculture, Washington, D.C., March 1986 edition, sections 6.011-6.013, Revised June 1987 (pages 6-35 through 6-65). The "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Alternative methods of analysis may be submitted to the Administrator to determine their acceptability based upon their accuracy, repeatability, reproducibility, and lowest level of reliable measurement, as demonstrated by at least 3 laboratories. Copies of AOAC's "Official Methods" may be obtained from: AOAC, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201. Copies of USDA's Chemistry Laboratory Guidebook may be obtained from: Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This incorporation by reference was approved by the Director of the Federal Register on December 30, 1981, and March 15, 1982. These materials are incorporated as they exist on the date of the approval. (A notice of any change in the sections of the AOAC methods or the Chemistry Laboratory Guidebook cited herein will be published in the Federal Register.) The plant quality control system shall be subject to periodic review, and the approval of such system may be terminated in accordance with § 318.4(g)(2) of this subchapter.

§ 319.6 Limitations with respect to use of Mechanically Separated (Species).

(a) Meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species.

(b) Mechanically Separated (Species) described in § 319.5 that has a protein content of not less than 14 percent and a fat content of not more than 30 percent may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except those listed in paragraph

(d) of this section.

(c) Mechanically Separated (Species) for processing described in § 319.5 may constitute up to 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition in Part 319 which establishes a maximum limit on the fat content of such meat food product except those listed in paragraph (d) of this section.

(d) Mechanically Separated (Species) and Mechanically Separated (Species) for processing described in § 319.5 shall not be used in baby, junior, or toddler foods, ground beef, hamburger, fabricated steaks (§ 319.15(a), (b), and (d)), barbecued meats (§ 319.80), roast beef-parboiled and steam roasted (§ 319.81), corned (cured) beef cuts (§§ 319.100-319.103), certain cured pork products (§§ 319.104(a)-(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

cured product of more than 20 percent over the weight of the fresh uncured brisket. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured brisket.

§ 319.102 Corned beef round and other corned beef cuts.

In preparing "Corned Beef Round" and other corned beef cuts, except "Corned Beef Briskets," the curing solution shall be applied to pieces of beef weighing not less than one pound and such application shall not result in an increased weight of the cured beef product of more than 10 percent over the weight of the fresh uncured beef cut. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured beef cut.

§ 319.103 Cured beef tongue.

In preparing "Cured Beef Tongue," the application of curing solution to the fresh beef tongue shall not result in an increase in the weight of the cured beef tongue of more than 10 percent over the weight of the fresh uncured beef tongue.

§ 319.104 Cured pork products.

(a) Cured pork products, including hams, shoulders, picnics, butts and loins, shall comply with the minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of Cured Pork Product	Minimum Meat PFF Percentage ^{1/}	Product Name and Qualifying Statements
Cooked ham, loin ^{2/}	20.5	(common and usual)
	18.5	(common and usual) With Natural Juices
	17.0	(common and usual) Water Added
	Less than 17.0	(common and usual) and Water Product--X% of Weight is Added Ingredients ^{3/}

^{1/} The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw, unprocessed pork expressed as a percent of the non-fat portion of the finished product; and compliance shall be determined under section 318.19 of this subchapter for domestic cured pork product and § 327.23 of this subchapter for imported cured pork product.

Type of Cured Pork Product	Minimum Meat PFF Percentage 1/	Product Name and Qualifying Statements
Cooked shoulder, butt, picnic <u>2/</u>	20.0	(common and usual)
	18.0	(common and usual) With Natural Juices
	16.5	(common and usual) Water Added
	Less than 16.5	(common and usual) and Water Product--X% of Weight is Added Ingredients <u>3/</u>
Uncooked cured ham, loin	18.0	Uncooked (common and usual)
	Less than 18.0	Uncooked (common and usual) and Water Product--X% of Weight is Added Ingredients <u>3/</u>
Uncooked cured shoulder, butt, picnic	17.5	Uncooked (common and usual)
	Less than 17.5	Uncooked (common and unusual) and Water Product--X% of Weight is Added Ingredients <u>3/</u>

2/ The term "cooked" is not appropriate for use on labels of cured pork products heated only for the purpose of destruction of possible live trichinae.

3/ Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product--20% of Weight is Added Ingredients. A prerequisite for label approval of these products is a quality control program.

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(b) Cured pork products for which there is a qualifying statement required in paragraph (a) of this section shall bear that statement as part of the product name in lettering not less than 3/8 inch in height, or in lettering not less than one-third the size of the largest letter in the product name if it is in the same color and style of print and on the same color background as the product name. However, the Administrator may approve smaller lettering for labeling of packages of 1 pound or less, provided such lettering is at least one-third the size and of the same color and style as the product name.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter.

(d) The binders provided in § 318.7(c)(4) of this subchapter for use in cured pork products may be used singly in those cured pork products labeled as "Ham water added" and "Ham and water product--X% of weight is added ingredients." These binders are not permitted to be used in combination with one or more such binders approved for use in cured pork products. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

§ 319.105 "Ham patties," "Chopped ham," "Pressed ham," "Spiced ham," and similar products.

(a) Finely divided (chopped, ground, flaked, chipped) cured ham products such as "Ham patties," "Chopped ham," "Pressed ham," and "Spiced ham" shall comply with minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of Cured Pork Product	Minimum Meat PFF Percentage <u>1/</u>	Product Name and Qualifying Statements
"Ham Patties" "Chopped Ham" "Pressed Ham," and "Spiced Ham"	19.5	(common and usual)
"Ham Patties" "Chopped Ham" "Pressed Ham," and "Spiced Ham"	17.5	(common and usual) With Natural Juices
"Ham Patties" "Chopped Ham" "Pressed Ham," and "Spiced Ham"	16.0	(common and usual) Water added

1/ The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw, unprocessed pork expressed as a percent of the nonfat portion of the finished product; and compliance shall be determined under section 318.19 of this subchapter.

Type of Cured Pork Product	Minimum Meat PFF Percentage 1/	Product Name and Qualifying Statements
"Ham Patties" "Chopped Ham" "Pressed Ham," and "Spiced Ham"	Less than 16.0	(common and usual) and Water Product-- (x)% of Weight is Added Ingredients <u>2/</u>

(b) Cured pork products prepared under this section except "Ham patties" may contain finely chopped ham shank meat to the extent of 25 percent over that normally present in boneless ham. Mechanically Separated (Species) Product may be used in accordance with § 319.6.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter, and those cured pork products prepared under this section for which there is a qualifying statement required shall comply with the requirements of § 319.104(b) of this subchapter.

(d) In addition to the other requirements of this section, "Ham Patties" may not contain more than 35 percent fat, by analysis.

§ 319.106 "Country Ham," "Country Style Ham," "Dry Cured Ham," "Country Pork Shoulder," "Country Style Pork Shoulder," and "Dry Cured Pork Shoulder."

(a) "Country Ham," "Country Style Ham," or "Dry Cured Ham," and "Country Pork Shoulder," "Country Style Pork Shoulder," or "Dry Cured Pork Shoulder," are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "ham," as specified in § 317.8(b)(13) of this subchapter, or from a single piece of meat from a pork shoulder. They are prepared in accordance with paragraph (c) of this section by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients as specified in paragraph (d) of this section. They may not be injected with curing solutions nor placed in curing solutions.

(b) The product must be treated for the destruction of possible live trichinae in accordance with such methods as may be approved by the Administrator upon request in specific instances and none of the provisions of this standard can be interpreted as discharging trichinae treatment requirements.

(c)(1) The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

2/ Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product--20% of Weight is Added Ingredients. A prerequisite for label approval of these products is a quality control program.

establishments shall apply to the Administrator for approval of their establishments for such purpose. Application shall be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C., and shall include all information called for by that form.

* (d) Approval for Federal import inspection shall be in accordance with part 304 of this subchapter. *

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 304.2(e), 307.1, 307.2(b), (d), (f), (h), (k), and (l) and 308.3, 308.4, 308.5, 308.6, 308.7, 308.8, 308.9, 308.11, 308.13, 308.14, and 308.15 of this subchapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed and drawings have been submitted in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. If it is determined that the establishment does not meet such requirements, approval of the establishment as an official import inspection establishment may be refused in accordance with the applicable rules of practice. A written notice, specifying the premises to which the approval applies, shall be given to each applicant granted approval. When approval is refused for any such reason, the applicant shall be informed of the action and the reason therefor. Approval may also be refused in accordance with § 401 of the Act and applicable rules of practice.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may also be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A sampling inspection shall be made, as provided in paragraph (a) of this section, of foreign chilled fresh or frozen fresh meat, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh meat shall be the same as those used for domestic chilled fresh or frozen fresh meat. (See § 327.21.)

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this Part are met, the determination of

(§ 327.6(j) continued)

the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(l) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product on Form MP-410 to Program area supervisors at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with § 318.309(d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this subchapter. The importers or his/her agent shall provide the necessary incubation facilities in accordance with § 318.309(d)(1)(i) of this subchapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this subsection may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 327.7 Products for importation; movement prior to inspection; handling; bond; assistance.

(a) No product required by this part to be inspected shall be moved, prior to inspection from any port, or, if arriving by water from the wharf where first unloaded, to any place other than the place designated by, or in accordance with, this part as the place where the same shall be inspected.

(b) No product required by this part to be inspected shall be conveyed, prior to inspection, from any port, or, if arriving by water, from the wharf where first unloaded, in any manner other than in compliance with this part.

(c) No product required by this part to be inspected shall be delivered to the consignee or his agent prior to inspection, unless the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(d) The consignee or his agent shall provide such assistance as Program inspectors may require for the handling and marking of product offered for entry.

§ 329.7 Procedure for seizure, condemnation, and disposition.

Any article or livestock subject to seizure and condemnation under this part shall be liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any United States district court, or other proper court specified in section 404 of the Act, within the jurisdiction of which the article or livestock is found.

§ 329.8 Authority for condemnation or seizure under other provisions of law.

The provisions of this part relating to seizure, condemnation and disposition of articles or livestock do not derogate from authority for condemnation or seizure conferred by other provisions of the Act, or other laws.

§ 329.9 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to bribery of Program employees, receipt of gifts by Program employees, and forcible assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act.

PART 330-[RESERVED]

PART 331--SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES;
AND FOR DESIGNATION OF ESTABLISHMENTS WHICH
ENDANGER PUBLIC HEALTH
AND FOR SUCH DESIGNATED ESTABLISHMENTS

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

SOURCE: The provisions of this Part 331 appear at 35 FR 1967, Dec. 29, 1970, unless otherwise noted.

§ 331.1 Definition of "State."

For purposes of this Part, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized Territory.

§ 331.2 Designation of States under paragraph 301(c) of the Act.

Each of the following States has been designated, under paragraph 301(c) of the Act, as a State in which the provisions of Titles I and IV of the Act shall apply to operations and transactions wholly within such State. The Federal provisions apply, effective on the dates shown below:

State	Effective date of application of Federal provisions
Arkansas.....	June 1, 1981
California.....	April 1, 1976
Colorado.....	July 1, 1975
Connecticut.....	October 1, 1975
Guam.....	January 21, 1972
Hawaii.....	November 1, 1995
Idaho.....	July 1, 1981
Kentucky.....	January 14, 1972
Maine.....	May 12, 1980
Maryland.....	March 31, 1991
Massachusetts.....	January 12, 1976
Michigan.....	October 3, 1981
Minnesota.....	May 16, 1971
Missouri.....	August 18, 1972
Nebraska.....	October 1, 1971
Nevada.....	July 1, 1973
New Hampshire.....	August 6, 1978
New Jersey.....	July 1, 1975
New York.....	July 16, 1975
North Dakota.....	June 22, 1970
Northern Mariana Islands.....	October 29, 1979
Oregon.....	July 1, 1972
Pennsylvania.....	July 17, 1972
Puerto Rico.....	June 18, 1971
Rhode Island.....	October 1, 1981
Tennessee.....	October 1, 1975
Virgin Islands.....	November 27, 1971
Washington.....	June 1, 1973

§ 331.3 States designated under paragraph 301(c) of the Act; application of regulations.

The provisions of the regulations in this subchapter apply to operations and transactions wholly within each State designated in § 331.2 under paragraph 301(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

* (a) Each establishment located in such a designated State, shall be granted *
* inspection required under § 302.1(a)(2) of this subchapter only if it is found, upon a *
* combined evaluation of its premises, facilities, and operating procedures, to be capable of *
* producing products that are not adulterated or misbranded. *

(b) Section 305.2 of this subchapter will apply to establishments required to have inspection under § 302.1(a)(2) of this subchapter, except that existing interconnections between official and unofficial establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of this subchapter. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible product does not enter the official establishment contrary to the regulations of this subchapter.

(c) Section 308.4 of this subchapter shall apply to such establishments, except that separate toilet rooms for men and women workers will not be required when the majority of the workers in the establishment are related by blood or marriage, provided that this will not conflict with municipal or State requirements; and except that separation of toilet soil lines from house

THE REVERSE OF THIS PAGE IS INTENDED TO BLANK.

(e) Products of the types specified in this section except those specified in paragraphs (c) and (d) of this section will be deemed to be represented as poultry products if the kind name of the poultry (chicken, turkey, etc.) is used in the product name of the product without appropriate qualification. For example, a consumer-packaged noodle soup product containing less than 2 percent chicken meat on a ready-to-serve basis may not be labeled "chicken Noodle Soup" but, when appropriate, could be labeled as "Chicken Flavored Noodle Soup." Products exempted under this section are subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

Subpart D-Application for Inspection; Grant or Refusal of Inspection

§ 381.16 How application shall be made.

The operator of each establishment of the kind required by § 381.6 to have inspection shall make application to the Administrator for inspection service. In cases of change of name, ownership, or location, a new application shall be made.

§ 381.17 Filing of application.

Every application for inspection at any establishment shall be made by the operator on a form furnished by the Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, and shall include all information called for by that form, including the name of any subsidiary corporation that will prepare any poultry product or conduct any other operation at the establishment for which inspection is requested. The applicant for inspection will be held responsible for compliance by all its subsidiaries with the requirements of the regulations at such establishments if inspection is granted. Processing of poultry products and other operations at the establishment for which inspection is granted may be conducted only by the applicant, except that such a subsidiary of the grantee, may conduct such operations at such establishment.

§ 381.18 Authority of applicant.

Any person applying for inspection service may be required at the discretion of the Administrator to demonstrate that the operator of the establishment authorized him to do so.

§ 381.19 Application for inspection; required facilities.

* All applicants for inspection whose operations include irradiation and other processing shall *
* submit, to the Administrator, a proposed quality control system as provided in § 381.149 of this *
* part. *

§ 381.20 Survey and grant of inspection.

* (a) Before inspection is granted, FSIS shall survey the establishment to determine if the *
* construction and facilities of the establishment are in accordance with the regulations. FSIS will *
* grant inspection, subject to § 381.21, when these requirements are met. *

- * (b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in
* the notice the establishment, including the limits of the establishment's premises, to which the
* grant pertains.

§ 381.21 Refusal of inspection.

(a) The Administrator may refuse to grant inspection at any establishment if he determines that it does not meet any requirements as to premises, facilities, and equipment, and the operation thereof, prescribed in the regulations under section 7 of the Act to prevent the distribution under the Act of adulterated poultry products, or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations. When inspection is refused for any such reason, the applicant shall be informed of the action and the reasons therefor and afforded an opportunity to present his views informally.

(b) If the refusal is based on a failure to comply with any requirements prescribed under section 7 of the Act, the applicant shall, upon his request, be afforded opportunity for a hearing in accordance with applicable rules of practice, with respect to the merits or validity of the action taken, but such refusal shall continue in effect unless otherwise ordered by the Secretary.

(c) Inspection may also be refused in accordance with section 18(a) of the Act and the applicable rules of practice.

(d) (1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters of the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended, to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within 1 year after receipt of such request. Further, upon receipt of an application for inspection and a certification as required by subsection 21(b) of the Federal Water Pollution Control Act, the Administrator (as defined in § 381.1) is required by paragraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that paragraph. No grant of inspection can be made until the requirements of said paragraph (2) have been met.

(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

Subpart E-Inauguration of Inspection; Official Establishment Numbers;
Separation of Establishments and Other Requirements;
Withdrawal of Inspection

§ 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§ 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§ 381.27 Inauguration of service; notification concerning regulations;
status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.

§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

§ 381.29 Suspension or other withdrawal of inspection service.

(a) Inspection service may be withdrawn in accordance with section 18 of the Act and the applicable rules of practice.

(b) During a period of withdrawal, no processing of poultry or poultry products subject to the inspection requirements of the Act shall be carried on in the official establishment. However, any product which was inspected and passed prior to the withdrawal may be shipped from the official establishment, provided its identity was maintained, and it has not become adulterated or misbranded.

(c) Inspection may be suspended, revoked, or terminated as provided in subsection 21(b) of the Federal Water Pollution Control Act, as amended.

(d) The assignment of inspectors may be temporarily suspended, in whole or in part, by the Administrator, to the extent he determines necessary to avoid impairment of the effective conduct of the inspection service when the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within the scope of his office, employment, or agency, threatens to forcibly assault or forcibly assaults, intimidates, or interferes with any inspection service employee in or on account of the performance of his official duties under the Act, unless promptly upon the incident being brought by an authorized supervisor of the Inspection Service employee to the attention of the operator of the establishment the operator (1) satisfactorily justifies the incident, (2) takes effective steps to prevent a recurrence, or (3) provides acceptable assurance that there will not be any recurrences. The suspension shall remain in effect until one of such actions is taken by the operator: Provided, That upon request of the operator he shall be afforded an opportunity for an expedited hearing to show cause why the suspension should be terminated.

Subpart F-Assignment and Authorities of Program Employees

§§ 381.30 - 381.31 (RESERVED)

§ 381.32 Access to establishments.

Any duly authorized representative of the Secretary shall have access at all reasonable times, by day or night, whether the establishment is in operation or not, to the premises or any part thereof of an establishment engaged in processing poultry or poultry products for commerce, upon presentation of appropriate credentials.

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle the inspector to admittance at all regular entrances and to all parts of the establishment and premises to which the inspector is assigned.

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: Provided, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when required, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of \$9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection: Provided further, That denial of a labeling application by the inspector-in-charge shall not constitute a basis for an appeal under this section.

Subpart G-Facilities for Inspection; Overtime and Holiday Service;
Billing Establishments

§ 381.36 Facilities required.

(a) Inspector's Office. Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for

Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) Facilities for ante-mortem inspection. Batteries, coops, or other facilities in which live poultry is presented for ante-mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out an adequate inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or "kickouts" shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspector. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall meet the requirements specified in § 381.53. The station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities complying with section 381.53(g)(4) of this Part shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A minimum of 200 foot-candles of shadow-free lighting with minimum color rendering index value of 85^{1/} where the birds are inspected to facilitate inspection, notwithstanding the requirements of § 381.52(b).

(viii) "Online" handrinsing facilities with a continuous flow of water conforming to § 381.51(f) shall be provided for and within easy reach of each inspector and each establishment helper.

(ix) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall conform to the requirements of § 381.53(m).

(2) The following provisions shall apply only to prechill and postchill reinspection stations:

(i) Floor space shall consist of a minimum of 3 feet along each conveyor line and after each chiller to allow carcasses to be removed for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 2 feet wide, 2 feet deep, and 3 feet high designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85^{1/} on the table surface shall be provided.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy access of persons working at the stations.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(d) Facilities for the New Line Speed (NELS) inspection system. The following requirements for lines operating under the NELS inspection system are in addition to the normal requirements to obtain a grant of inspection and to the requirements for NELS in § 381.76(b) and (c).

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (d)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 6 feet along the conveyor line for the establishment employee presenting the birds, 4 feet for the inspector, and 4 feet for the establishment helper. A total of at least 42 feet along the conveyor line shall be supplied for three inspection stations.

(iii) Selectors or "kickouts" shall be installed so the three inspection stations will receive birds on 18-inch centers with no intervening birds to impede inspection. The selector must move the

^{1/} This requirement may be met by deluxe cool white type of fluorescent lighting.

bird to the end of the trough for the presenter, inspector, and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid splashing the mirror (paragraph (d)(1)(vii) of this section) and swinging when entering the inspection station. Guide bars shall not extend in front of the inspection station mirror to avoid obstructing the inspector's view.

(iv) Each inspector's station shall have an easily and rapidly adjustable platform, with a minimum of 14 inches of vertical adjustment, which covers the entire length of the station (4 feet) and has a minimum width of 2 feet. The platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough complying with § 381.53(g)(4) of this Part shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A distortion-free mirror, at least 3 feet wide and 2 feet high, shall be mounted at each inspection station so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection platform so that the inspector can position himself/herself opposite it 8 to 12 inches from the downstream edge. The mirror must be maintained abrasion free.

(viii) A minimum of 200 foot-candles of shadow-free lighting with minimum color rendering index value of 85^{1/} where the birds are inspected to facilitate inspection, notwithstanding the requirement of § 381.52(b). A light shall also be positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surfaces.

(ix) "On-line" handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment presenter and helper.

(x) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(xi) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall conform to the requirements of § 381.53(m).

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of 6 feet along the conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

^{1/} This requirement may be met by deluxe cool white type of fluorescent lighting.

(iii) A table, at least 3 feet wide and 2 feet deep, shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow free lighting with a minimum color rendering index of 85^{1/} on the table surface.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(e) Facilities for the New Turkey Inspection (NTI) System. The following requirements for lines operating under the NTI System are in addition to the normal requirements to obtain a grant of inspection and to the requirements for the NTI System in § 381.76(b) and (c).

(1) The following provisions apply to every inspection station:

(i) The conveyor line must be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (e)(1)(iii) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 8 feet along the conveyor line; at least 4 feet for the inspector, and at least 4 feet for the establishment helper.

(iii) The inspector's station shall have an easily and rapidly adjustable platform with a minimum width of 2 feet which covers the entire length of the station (4 feet). The platform must adjust vertically a minimum of 14 inches, and must have a 42-inch rail on the back side and ½-inch foot bumpers on the sides and the front to allow safe working conditions.

(iv) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(v) A trough or other facilities complying with § 381.53(g)(4) shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be wide enough to prevent trimmings, drippage, and debris from accumulation on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to prevent contamination of carcasses by splash.

(vi) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index value of 85^{1/} where the birds are inspected to facilitate inspection is required. The minimum lighting requirement for inspection stations in § 381.52(b) shall not apply.

(vii) On-line handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

(ix) Receptacles shall be provided for condemned carcasses and parts conforming with the requirements of § 381.53(m).

(2) The following provisions shall apply only to the reinspection station:

^{1/} This requirement may be met by deluxe cool white type of fluorescent lighting.

(§ 381.36(e) continued)

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85^{1/} at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

§ 381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5 ½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of § 381.38: Provided, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in § 381.145(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of

^{1/} This requirement may be met by deluxe cool white type of fluorescent lighting.

inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: Provided, however, Minor deviations from a daily operating schedule may be approved by the inspector-in-charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: Provided, That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall be the holiday.

§ 381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 381.38(a) and at the rate specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

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Number of persons of same sex:	Minimum number of facilities
1 to 9.....	1
10 to 24.....	2
25 to 49.....	3
50 to 74.....	4
75 to 100.....	5
Over 100.....	1 for each additional 30 persons.

Where 10 or more are employed, urinals may be substituted for the toilet bowls specified in the foregoing formula, except that the number of toilet bowls in such cases may not be reduced to less than two-thirds of the number specified. Two feet of trough urinal shall be considered as equivalent to one individual urinal.

- (i) Suitable sanitary drinking water facilities shall be provided.
- (j) All toilets, lavatories, and other sanitary facilities shall be kept clean and in good repair.

§ 381.52 Lighting and ventilation.

(a) There shall be ample light, either natural or artificial or both, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary conditions.

(b) All rooms in which poultry is killed, eviscerated, or otherwise processed shall have at least 30 foot-candles of light intensity on all working surfaces, except that at the inspection stations such light intensity shall be of 50 foot-candles. In all other rooms there shall be provided at least 5 footcandles of light intensity when measured at a distance of 30 inches from the floor.

(c) All rooms shall be adequately ventilated to eliminate objectionable odors and minimize moisture condensation.

§ 381.53 Equipment and utensils.

- * (a) Equipment and utensils used for processing or otherwise handling any edible poultry *
* product or component ingredient shall comply with applicable provisions of paragraphs (b) *
* through (l) of this section and otherwise shall be of such material and construction as will *
* facilitate their thorough cleaning, ensure cleanliness in the preparation and handling of all *
* edible poultry products, and avoid adulteration and misbranding of such products. In *
* addition to these requirements, equipment and utensils shall not in any way interfere with or *
* impede inspection procedures. Receptacles used for handling inedible products shall be of *
* such material and construction that their use will not result in adulteration of any edible *
* product or in unsanitary conditions at the establishment, and they shall bear conspicuous and *
* distinctive marking to identify them as only for such use and shall not be used for handling *
* any edible poultry products. *
- * (b) Refuse containers. Leakproof refuse containers with covers shall be provided, except *
* that perforated containers may be used for the temporary collection of feathers *
* and such containers need not be covered. *

- * (c) Scalding equipment. (1) Scalding tanks shall be constructed and installed so as to prevent contamination of potable water lines and to permit water to enter continuously at a rate which will result in a sanitary scalding operation. The rate of flow necessary to maintain a sanitary scalding operation will be determined on such factors as the class of poultry and the number of birds per minute going into the scalding tank. It shall be the responsibility of the inspector in charge to establish a minimum rate of flow for each scalding tank in each official establishment. *
- (2) The overflow outlets in scalding equipment shall be of sufficient size to permit feathers and water to be carried off.
- (3) The overflow, draw off valves, and sediment basin drain shall discharge into a floor or valley drain, or onto the floor in proximity to a floor or valley drain.
- * (d) Wax finishing. When wax dipping is used, metal troughs shall be provided to catch the wax removed from the dipped poultry. Acceptable facilities and methods shall be employed in reclaiming the wax. *
- * (e) Ice shovels. Ice shovels shall be smooth surfaced and entirely constructed of rustproof, impervious material. *
- * (f) Conveyors. (1) Conveyors used in the preparation of ready-to-cook poultry shall be of metal or other acceptable material and of such construction as to permit easy identification of the viscera with their carcass and so designed as will present each carcass or all parts thereof in a way that will permit adequate and efficient inspection. *
- (2) Overhead conveyors shall be so constructed and maintained that they will not allow grease, oil, or dirt to accumulate on the drop chain or shackle, which shall be of noncorrosive metal.
- (3) Nonmetallic belt-type conveyors used in moving poultry products shall be of waterproof composition.
- (4) When eviscerated on a conveyor, each carcass shall be suspended and a trough or other acceptable facilities for maintaining proper sanitation shall be provided beneath the conveyor. Such troughs or other facilities shall be flushed or cleaned in an acceptable manner and shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the viscera have been completely removed.
- * (g) Chilling and thawing tanks. Chilling and thawing tanks shall be constructed of metal or other suitable material impervious to moisture and shall be of sanitary construction with edges rolled outward. Where mechanical devices are not used for removing carcasses from the chilling or thawing tanks, the tanks shall be of a size that will enable employees to remove poultry without entering the tanks. *
- * (h) Tables. Inspection, eviscerating, and cutting tables shall be made of metal or other acceptable material, have coved corners, and be constructed and placed so as to permit thorough cleaning. *
- * (i) Plants lacking conveyors. In plants where no conveyors are used, each carcass shall be eviscerated in an individual metal tray of seamless construction or in a tray of other acceptable material and construction. *
- * (j) Water spray washing equipment. Water spray washing equipment with sufficient water pressure to thoroughly and efficiently wash carcasses shall be used for washing carcasses inside and out. *

(§ 381.53 continued)

- * (k) Offal receptacles. Watertight receptacles constructed of metal or other acceptable impervious material shall be used for entrails and other waste resulting from preparation of eviscerated poultry. *
- * (l) Receptacles for condemned carcasses. Watertight receptacles for holding or handling condemned carcasses or parts of carcasses shall be so constructed as to be readily and thoroughly cleaned; such receptacles shall be marked in a conspicuous manner with the words "U.S. Condemned" in letters not less than 2 inches high and when required by the inspector in charge, shall be equipped with facilities for locking and sealing. *

§ 381.54 Accessibility of equipment.

(a) General. All equipment shall be placed so as to be readily accessible for all processing and cleaning operations.

(b) Mechanical pickers. When mechanical pickers are used, they shall be installed so as to be accessible for thorough cleaning and removal of the accumulation of feathers.

§ 381.55 Restrictions on use of equipment and utensils.

Equipment and utensils used in the official establishment shall not be used outside the official establishment, except under conditions prescribed or approved by the Administrator in specific cases. Equipment used in the preparation of any article (including, but not limited to, animal food), from inedible material shall not be used outside of the inedible products department except under such conditions as may be prescribed or approved by the Administrator in specific cases.

§ 381.56 Maintenance of sanitary conditions and precautions against contamination of poultry products.

The premises of the official establishment shall be kept free from refuse, waste materials, and all other sources of odors and conditions that may result in adulteration of the poultry products handled at the establishment.

§ 381.57 Cleaning of rooms and compartments.

Rooms, compartments, and other parts of the official establishment shall be kept clean and in sanitary condition and good repair.

§ 381.58 Cleaning of equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling any poultry or poultry product shall be kept clean, sanitary, and in good repair.

(b) Batteries and dropping pans shall be cleaned regularly and the manure removed from the official establishment daily.

(c) Scalding tanks shall be completely emptied and thoroughly cleaned as often as may be necessary, but not less frequently than once a day when in use.

(d) All equipment and utensils used in the killing, roughing, and pinning rooms shall be thoroughly washed and cleaned at least once daily when in use.

(e) The chilling and packing room and equipment and utensils used therein shall be maintained in a clean and sanitary condition.

(f) Chilling or thawing tanks shall be emptied after each use. They shall be thoroughly cleaned at least once daily when in use, except that when the same poultry is held therein in excess of 24 hours, the tanks shall be thoroughly cleaned after the poultry is removed therefrom and prior to reuse.

(g) Conveyor trays or belts which come in contact with raw poultry products shall be completely washed and sanitized after each use.

(h) Tables, shelves, bins, trays, pans, knives, and all other tools and equipment used in the processing of poultry products shall, after cleaning, be drained on racks and trays and pans shall not be nested.

(§ 381.121b (c) continued)

Chapter 4 Methods of Test for Packages Labeled by Volume

4.6.4. Method D: Determining the Net Contents of Compressed Gas in Cylinders

4.7. Milk

4.16. Fresh Oysters Labeled by Volume

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

Supplement 3

Chapter 3 Methods of Test for Packages Labeled by Weight

3.17. Flour and Dry Pet Food

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

5.5. Paper Plates

5.8. Baler Twine

Appendix A. Forms and Worksheets

Supplement 4

3.11 Aerosol Packages

3.11.1 Equipment

3.11.2 Preparation for Test

3.11.3 The Determination of Net Contents: Part 1

3.11.4 Exhausting the Aerosol Container

3.11.5 The Determination of Net Contents: Part 2

Appendix A. Report Forms

§ 381.121c Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weigh poultry products sold or otherwise distributed in commerce in federally inspected poultry plants shall be installed, maintained, and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology (NIST) Handbook 44, "Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices," 1994 Edition, October 1993, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and accordance with 5 U.S.C. 552(a) and

accordance with 5 U.S.C. 552(a) and are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the Federal Register. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC. 20402. It is also available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, DC 20408.

(b) All scales used to weigh poultry products sold or otherwise distributed in commerce or in States designated under section 5(c) of the Poultry Products Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh poultry products unless it has been found upon test and inspection as specified in NIST Handbook 44 to provide accurate weight. If a scale is inspected or tested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been reinspected and retested by a USDA official, or a State or local government weights and measures official, or a State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a "Retain" tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

§ 381.121d Scales; Testing of.

(a) The operator of each official establishment that weighs poultry food products shall cause such scales to be tested for accuracy in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have a net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with section 381.145 of this subchapter.

§ 381.121e Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with section 381.121b of this subchapter shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section, and be reinspected in accordance with the requirements of this Part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

SUBPART O-ENTRY OF ARTICLES INTO OFFICIAL ESTABLISHMENTS;
PROCESSING INSPECTION AND OTHER REINSPECTIONS;
PROCESSING REQUIREMENTS

* § 381.145 Preparation of products to be officially supervised; responsibilities of official
* establishments; establishment operated quality control.

*
*

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in section 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with sections 381.115 or 381.205, except that poultry products inspected and passed and identified as such under the laws of an "at least equal" State or territory listed in section 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in section 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in section 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law. Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence.

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The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.

(c) Applying for Total Plant Quality Control. Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those Subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the

¹ Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisor. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved.

parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action -- ranging from the least to most severe: Provided, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

* (d) Partial Quality Control Programs. (1) Any owner or operator of an official establishment preparing poultry products who is required to have a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees. *

(2)(i) This quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action--ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

* (e) Evaluation and Approval of Quality Control or Systems. *

(1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section or § 381.149 of this subpart. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system, or quality control system for irradiation facilities will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulation thereunder, the total quality control system, or quality control system for irradiation facilities will be approved and plans will be made for implementation under departmental supervision. *

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with this notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding. *

- (3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or quality control system for irradiation facilities to assure compliance with the requirements of the Act and regulations thereunder. With the exception of a quality control system for irradiation facilities, as specified in § 381.149 of this Subpart, the Secretary shall continue to provide the Federal inspection necessary to carry out the responsibilities of the Act.

(f) Labeling Logo. Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Subparts M and N of this part.



- (g) Termination of Quality Control Systems.
- (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.
- (2) The approval of a total plant quality control system or a quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:
- (i) If adulterated or misbranded poultry product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.
- (ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this Subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)(1) Operating Schedule Under Total Plant Quality Control. An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) Application. Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

(3) Monitoring by Inspectors. In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(i) Containers with substances approved for use in the processing of products in section 381.147(f)(3) of this subchapter which enter any official establishment for use in poultry scald water shall, at all times, while they are in such establishment, bear labels showing the chemical names of the substances in such preparations. In the case of preparations containing substances which may be used under section 381.147(f)(3) only in limited amounts, the container labels shall also show the percentage of each such substance in the preparation and shall provide dilution directions which prescribe the maximum allowable use concentration of the preparation.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

The provisions of the regulations in this part apply to operations and transactions wholly within each State designated in § 381.221 under paragraph 5(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

* (a) Each establishment, located in such a designated State, which is granted inspection *
* required under § 381.6(b) only if it is found, upon a combined evaluation of its premises, *
* facilities, and operating procedures, to be capable of producing products that are not adulterated *
* or misbranded. *

(b) Section 381.26 will apply to establishments required to have inspection under § 381.6(b), except that existing interconnections between official and unofficial establishments or between official establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible poultry product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of the regulations. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible poultry product does not enter the official establishment contrary to the regulations.

(c) Sections 381.49 and 381.51 shall apply to such establishments, except that separate facilities for men and women workers will not be required when the majority of the workers in the establishment are related by blood or marriage, provided that this will not conflict with municipal or State requirements; and except that separation of toilet soil lines from house drainage lines to a point outside the buildings will not be required in existing construction when positive acting backflow devices are installed.

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Circuit Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 381.132, will be granted by the Circuit Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by paragraph 4(h) of the Act.

(2) The Circuit Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the Washington, D.C., office of the Labels and Packaging Staff and will retain one copy in a temporary approval file for the establishment.

(§ 381.222(d) continued)

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Circuit Supervisor (showing any modifications required by the Circuit Supervisor) to the Washington, D.C. office of the Labels and Packaging Staff, Meat and Poultry Inspection, Food Safety and Quality Service, USDA, Washington, D. C. 20250, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Circuit Supervisor must receive approval as required by § 381.132 or their use must be discontinued.

(4) The Circuit Supervisor will also review all shipping containers to insure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

(e) Sections 381.175 through 381.179 apply to operations and transactions not in or for commerce in a State designated under paragraph 5 (c) only if the State is also designated under section 11 of the Act and if such provisions are applicable as shown in § 381. 224.

(f) Section 381.185 (a) will not apply to States designated under paragraph 5(c) of the Act.

(g) Provisions of this part relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

§ 381. 223 Control and disposition of nonfederally inspected poultry products in States designated under paragraph 5(c) of the Act.

Upon the effective date of designation of a State under paragraph 5(c) of the Act, no poultry products can be processed within the State unless they are prepared under inspection pursuant to the regulations or are exempted from the requirement of inspection under § 381.10, and no unexempted poultry products which were processed without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, poultry products which were processed in any State listed in § 381.187 and inspected and, passed under the supervision of a responsible State or local inspection agency or exempted from State inspection can be distributed solely within the State, provided they are not adulterated or

§ 381.308 Deviations in processing

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) shall be handled under quality control as provided in paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(c) Any partial quality control program or any portion of a total quality system for handling process deviations shall be prepared in accordance with §381.145 of this subchapter.

(d) Handling process deviations without an approved quality control program.

(1) Deviations identified in process. If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or,

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 381.302(a) and (b) and is filed with the inspector in accordance with § 381.302(c); or,

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(a) A complete description of the deviation along with all necessary supporting documentation;

(b) A copy of the evaluation report; and,

(c) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with (iii) shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1)(iii) and (iv) of this section or in accordance with the following procedures:

(a) Emergency stops.

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 381.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed,

repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort Shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 381.306.

(b) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10°F (or 5.5°C) either (i) all containers in the retort shall be given an emergency still process (developed per § 381.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process (developed per § 381.302(b)) shall be used before container entry to the retort is restarted; or (iii) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) For temperature drops 10°F (or 5.5°C) or more, all containers in the retort shall be given an emergency still process (developed per § 381.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in

§ 381.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) Deviations identified through record review. Whenever a deviation is noted during review of the processing and production records required by § 381.307(a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(e) Process deviation file. The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 381.307(e) and shall be made available to Program employees upon request.

Approved by the Office of Management and Budget under control number 0583-0015]

§ 381.309 Finished product inspection

(a) Finished product inspections shall be handled under quality control as provided in paragraph (b) or paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(b) Any partial quality control program for finished product inspection shall be prepared in accordance with § 381.145 of this Part.

(c) That portion of a total quality control system for finished product inspection shall be prepared in accordance with § 381.145 of this Part.

(d) Handling finished product inspections without an approved quality control program.

(1) Incubation of shelf stable canned product.

(i) Incubator. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) Incubation temperature. The incubation temperature shall be maintained at $95 \pm 5^{\circ}\text{F}$ ($35 \pm 2.8^{\circ}\text{C}$). If the incubation temperature falls below 90°F (or 32°C) or exceeds 100°F (or 38°C) but does not reach 103°F (or 39.5°C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103°F (or 39.5°C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) Product requiring incubation. Shelf stable product requiring incubation includes:

(a) Low acid products as defined in § 381.300(m); and

(b) Acidified low acid products as defined in § 381.300(b).

(iv) Incubation samples.

(a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) Incubation time. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (a)(2) of this section.

(vi) Incubation checks and record maintenance. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before

a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers

incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 381.307(e).

(vii) Abnormal containers. The finding of abnormal containers (as defined in § 381.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) Shipping. No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion of the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) Container condition.

(i) Normal containers. Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) Abnormal containers. When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormalities in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

[Approved by the Office of Management and Budget under control number 0583-0015]

§ 381.310 Personnel and Training

All operators of thermal processing systems specified in § 381.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

§ 381.311 Recall Procedure

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

(Reporting requirements approved by the Office of Management and Budget under OMB #0583-0015.)

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